K023469

510(k) Summary
(As required by 21 C.F.R. §807.92)

Submitted by:	Ileana Yanes Victus, Inc. 4918 S.W. 74 Court Miami, Fl 33155 Tel: (305) 663-2129 ext 102. Fax: (305) 663-1843
Date of Summary	October 7, 2002
Device name	Victus IV Administration Sets (27058, 27059, 27062)
Common name	Intra Vascular Administration Set
Classification name	Regulation Number: 21 C.F.R §880.5440 Classification Name: Intra Vascular Administration Set
Predicate Devices	BBraun-McGaw IV Administration Sets (Pre-Amendment, and as modified by K921860 and K93265)
Modifications	There are no modifications to the device design that affect safety & effectiveness of the Victus IV Administration Sets.
Device Description	The Victus Administration Sets are single use, sterile, non-pyrogenic devices used to administer IV fluids/medication to a patient's vascular system via gravity control.
Intended Use	To administer IV fluids/medication to the patient's vascular system.
Technological characteristics	The Victus IV Administration Sets have the same technological characteristics as the legally marketed predicate IV Administrations Sets.
Testing	The Victus Administration Sets have undergone performance and safety testing to verify mechanical properties and biocompatibility using FDA recognised standards, where applicable.

DEC 1 0 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2002

Ms. Ileana Yanes
Regulatory Affairs
Victus, Incorporated
4918 S.W. 74 Court
Miami, Florida 33155

Re: K023469
Trade/Device Name: Victus I.V. Administration Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 15, 2002
Received: October 16, 2002

Dear Ms. Yanes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023469

Indications for Use Statement

510(k) Number
(if known)

Device Name Victus I.V. Administration Set

Indications for Use To administer IV fluids/medication to the patient's vascular system.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

Rebecca Cucenba

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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